

QA: QA

**U.S. DEPARTMENT OF ENERGY
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
OFFICE OF QUALITY ASSURANCE**

**REPORT FOR COMPLIANCE-BASED AUDIT OCRWMC-LLNL-04-07
OF LAWRENCE LIVERMORE NATIONAL LABORATORY
IN LIVERMORE, CALIFORNIA**

APRIL 19 - 23, 2004

Prepared by: _____
Patrick V. Auer
Audit Team Leader
Navarro Quality Services

Date: _____

Concurred by: _____
Robert F. Hartstern
Quality Verification Manager
Bechtel SAIC Company, LLC

Date: _____

Approved by: _____
Kerry M. Grooms
Team Lead, Assessments
Office of Quality Assurance

Date: _____

EXECUTIVE SUMMARY

A team of auditors representing the Office of Civilian Radioactive Waste Management (OCRWM) performed a compliance-based audit of the Lawrence Livermore National Laboratory (LLNL) in Livermore, California, from April 19 to 23, 2004. The audit scope included evaluation of the adequacy and implementation of quality-affecting procedures that implement the LLNL scope of work for compliance with the requirements described in DOE/RW-0333P, Revision 14, *Quality Assurance Requirements and Description* (QARD). The audit team evaluated the QARD; Office of Civilian Radioactive Waste Management (OCRWM) Administrative Procedures (AP), Bechtel SAIC Company, LLC (BSC) Line Procedures (LP), LLNL Quality Procedures (QP), and Technical Implementing Procedures (TIP).

The audit resulted in the following five condition reports (CR); similar conditions were grouped under a single CR to facilitate development of appropriate corrective action to preclude recurrences:

1. CR 2517 - Records not submitted within 60 days
2. CR 2518 - No final compliance review was performed for scientific notebook
3. CR 2519 - Incorrect forms used by LLNL
4. CR 2520 - LLNL Electronic Management of Data Checklist not transmitted
5. CR 2521 - Employee not listed on training matrix

The audit team concluded that the quality-affecting APs, LPs, QPs, and TIPs adequately implement the QARD requirements. In addition, the team determined that LLNL has been implementing the quality-affecting procedures in an overall satisfactory manner.

1.0 INTRODUCTION

1.1 PURPOSE AND SCOPE

A team of auditors representing OCRWM performed a compliance-based audit of LLNL in Livermore, California, from April 19 to 23, 2004. The audit scope included evaluation of quality-affecting APs, LPs, QPs, and TIPs that implement the LLNL scope of work for compliance with the requirements described in the following documents:

- QARD, Sections 1.0, 2.0, 5.0, 6.0, 7.0, 12.0, 15.0, 16.0, 17.0, and Supplements I, II, III & V
- OCRWM APs
- BSC LPs
- LLNL QPs
- LLNL TIPs

1.1 AUDIT TEAM

Patrick V. Auer, Navarro Quality Services (NQS)/Audit Team Leader
John R. Doyle, NQS/Auditor
Kristi A. Hodges, NQS/Auditor
Alan B. Duncan, BSC/Auditor
Stephen F. Schuermann, BSC/Auditor

2.0 AUDIT DETAILS

A pre-audit meeting was held April 19, 2004, to review the audit scope with management. The team held daily meetings to discuss the progress and status of the audit, including potential adverse conditions. The Audit Team Leader held daily meetings to inform LLNL management of the audit issues and status. The Audit Team Leader conducted a post-audit meeting on April 23, 2004, to summarize the results of the audit.

Attachment A, Personnel Contacted, lists persons who attended the pre- and post-audit meetings. Attachment B, Summary of Audit Results, lists the results by QARD Section and implementing document.

QARD Section 1.0

The audit team evaluated records associated with the implementation of 033-YMP-QP 1.0, *Organization*, including Attachment A, the current LLNL organization chart.

The latest revision of the procedure was adequate and all revisions that were used were effectively implemented.

QARD Section 2.0

The audit team evaluated records associated with the implementation of the following:

- AP-2.1Q, *Personnel Training and Qualification*, including completion of required training and the current LLNL Employee-to-Job-Function Matrix
- LP-2.9Q-BSC, *Establishment and Verification of Required Education and Experience of Personnel*, including completion of required Verification of Education and Experience (VoEE)
- AP-2.27Q, *Planning for Science Activities*, including technical work plans

The latest revision of the procedures was adequate and all revisions that were used were effectively implemented except as identified in Level B CR 2519, which describes the use of incorrect VoEE forms, and Level C CR 2521, which describes an employee not listed on Employee Job Function Matrix.

QARD Section 5.0

The audit team evaluated records associated with the implementation of the following:

- 033-YMP-QP 2.1, *Preparation, Approval and Revisions of Procedures*, including preparation and revision of QPs and their associated review and records packages
- 033-YMP-QP-5.0, *Technical Implementing Procedures*, including preparation and revision of TIPs and their associated review and records packages

The latest revision of the procedures was adequate and all revisions that were used were effectively implemented except as identified in Level B CR 2517, which details records that were not submitted within 60 days.

QARD Section 6.0

The audit team evaluated records associated with the implementation of the following:

- AP-2.14Q, *Document Review*, including review of technical data packages
- AP-6.1Q, ICN 2, *Document Control*, including use and availability of controlled documents, document master list, and use of document identifiers

The latest revision of the procedures was adequate and all revisions that were used were effectively implemented except as previously identified in CR 2519 on incorrect forms.

QARD Section 7.0

The audit team evaluated records associated with the implementation of the following:

- AP-7.7Q, *Acceptance of Items and Services*, including acceptance reports for scientific investigation and calibration services
- TIP-AC-10, *Q-Procurement of Analytical Services from a Non-QSL Laboratory*, including quality control sample plans

The latest revision of the procedures was adequate and all revisions that were used were effectively implemented except as the previously identified in CR 2519 on incorrect forms.

QARD Section 12.0

The audit team evaluated records associated with the implementation of the following:

- AP-12.1Q, *Control of Measuring and Test Equipment and Calibration Standards*, including calibration reports, documentation of use of Measuring and Test Equipment (M&TE) in scientific notebooks, out of tolerance reports, standards, handling and storage of M&TE, calibration status, and labeling.
- TIP-CM-42, *User Verification of Gamry Potentiostats*, including documentation of calibration, description of calibration method, and identification of standards.

The latest revision of the procedures was adequate and all revisions that were used were effectively implemented.

QARD Section 15.0

There was no implementation of Section 15.0 at LLNL.

QARD Section 16.0

The audit team evaluated records associated with the implementation of the following:

- AP-16.1Q, *Condition Reporting and Resolution*, including effectiveness reviews of closed CRs
- AP-16.4Q, *Causal Analysis and Corrective Action Plan Development*, including causal analysis reports and corrective actions

The latest revision of the procedures was adequate and all revisions that were used were effectively implemented.

QARD Section 17.0

The audit team evaluated records associated with the implementation of AP-17.1Q, *Records Management*, including the file plan, record problem reports, records packages, and records transmittals.

The latest revision of the procedure was adequate and all revisions that were used were effectively implemented except as in the previously identified CR 2517 on records not submitted within 60 days.

QARD Supplement I

The audit team evaluated records associated with the implementation of AP-SI.1Q, *Software Management*, including software user requests, software codes on baseline, installation checkout documentation, use of software in model reports, and configuration management. There was not implementation of AP-SI.2Q, AP-SI.3Q, and AP-SI.4Q.

The latest revision of the procedure was adequate and all revisions that were used were effectively implemented.

QARD Supplement II

The audit team evaluated records associated with the implementation of the following:

- 033-YMP-QP 8.0, *Identification and Control of Samples*, including sample identification, sample collection records, and scientific notebooks
- 033-YMP-QP 13.0, *Handling, Storage, and Shipping*, including handling, shipping and storage, and scientific notebooks
- TIP-CM-01, *Accounting of Test Specimens for the Long-Term Corrosion Storage*, including specimens and scientific notebooks
- TIP-CM-02, *Receiving Control for LLNL Receipt and Tracking of Specimens Procured under M&O Quality Affecting (Q) Procurements*, including handling and storage of specimens and scientific notebooks
- TIP-YM-03, *Labeling, Tracking, and Shipping of Samples*, including sample transmittal form and scientific notebooks

The latest revision of the procedures was adequate and all revisions that were used were effectively implemented. There was no implementation of AP-SII.2Q, AP-SII.3Q, and TIP-CM-22 at LLNL.

QARD Supplement III

The audit team evaluated records associated with the implementation of the following:

- AP-SIII.1Q, *Scientific Notebooks*, including scientific notebooks, initial and in-process entries, compliance review, and technical reviews
- AP-SIII.3Q, *Submittal and Incorporation of Data to the Technical Data Management System*, including technical data packages, technical data information forms, technical review packages, records road maps, Impact Review Action Notices, and Automated Technical Data Entry screens
- AP-SIII.9Q, *Scientific Analyses*, including analysis reports
- AP-SIII.10Q, *Models*, including model reports

The latest revision of the procedures was adequate and all revisions that were used were effectively implemented except as identified in CR 2518, which describes the lack of final compliance review for one scientific notebook. There was no implementation of AP-SIII.2Q at LLNL.

QARD Supplement V

The audit team evaluated records associated with the implementation of the following:

- AP-SV.1Q, *Control of Electronic Management of Information*, including process control evaluations, technical work plans, and scientific notebooks
- 033-YMP-QP 3.8, *Control of Electronic Management of Data*, including electronic management of data checklists and scientific notebooks

The latest revision of the procedures was adequate and all revisions that were used were effectively implemented except as identified in CR 2520, which describes the incomplete transmittal of a LLNL Electronic Management of Data Checklist.

3.0 SUMMARY OF AUDIT RESULTS

3.1 CONDITION REPORTS

The audit team identified four Level B conditions and one Level C condition. There were no Level A or D conditions and no noteworthy practices. Corrective actions for previously identified deficiency report BSC(B)-03-D-142 and CR 84 were found effective.

3.1.1 Adverse Conditions (Level B)

3.1.1.1 CR 2517 - Records not submitted within 60 days

Of the five QPs and TIPs procedure revision packages reviewed, the audit team found that four procedure review packages were not sent to the Records Processing Center (RPC) within 60 days.

Requirement

AP-17.1Q, Revision 2, ICN 5, *Records Management*, Attachment 1, Section A.1 c)1) states: "Submit all QA records (individual or records packages) to the RPC within 60 calendar days of stamping, initialing, or signing and dating as completed."

Condition

Records packages for the following LLNL procedures were not sent to the RPC within 60 days of completion:

1. 033-YMP-QP-8.0, Revision 2, CN 5
2. TIP-AC-13, Revision 0, CN 1
3. TIP-AC-01, Revision 0, CN 1
4. TIP-CM-11, Revision 0, CN 1

3.1.1.2 CR 2518 – No final compliance review was performed for scientific notebook

Five scientific notebooks were reviewed; the audit team found one instance of no final compliance review.

Requirement

AP-SIII.1Q, Revision 2, *Scientific Notebooks*, Section 5.7.2, requires the Responsible Manager or PI to, “a) Sign and date in the scientific notebook an approval for segment completion or closure of the notebook and forward the notebook, including all supplements referenced in the notebook, for Compliance Review (see Subsection 5.5).”

Condition

There was no final compliance review for scientific notebook SN-LLNL-SCI-465 V2.

3.1.1.3 CR 2519 – Incorrect forms used by LLNL

Of the 18 VoEE forms and 22 Acceptance Reports reviewed, the audit team found 10 instances of incorrect or out of date forms used.

Requirement

AP-6.1Q, Revision 7, ICN 2, *Document Control*, Section 5.6.2, Users of Controlled Documents, states: “a) Ensure the current revision of the controlled document is used in performance of work . . .”; and “c) When work cannot be accomplished as described in the implementing document, or accomplishment of such work would result in an undesirable condition, suspend the work.”

Condition:

Multiple instances of using out-of-date forms were identified. VoEE forms for five LLNL employees were from LP-2.13Q-OCRWM rather from LP-2.9Q-BSC. Out-of-date forms were used for acceptance reports for purchase order (PO) BA003631 to Micro Precision, dated August 29, 2003 and July 21, 2003; PO TA003347 to Heusser Neweigh, dated June 21, 2003 and June 23, 2003; and PO B01195 release FY-09-10 to Laboratory Testing, Inc., dated June 19, 2003.

3.1.1.4 CR 2520 – LLNL Assessment of Electronic Data Checklist not sent to Director, Office of Information Management

Of the two scientific notebooks reviewed, the audit team found one instance of incomplete transmittal of the data checklist.

Requirement

033-YMP-QP-3.8, Revision 1, CN 4, *Control of Electronic Management of Information*, states: “Attach the completed Electronic Management of Data Checklist to the completed OCRWM Process Control Evaluation for Supplement V Form and transmit the originals to the Director, Office of Information Management and Assistant Manager, Office of Project Execution.”

Condition

The completed Electronic Management of Data Checklist for SN-LLNL-SCI-482, dated February 17, 2004, was not transmitted to the Director, Office of Information Management or Assistant Manager, Office of Project Execution.

3.1.2 Minor Conditions Adverse to Quality (Level C)

3.1.2.1 CR 2521 – *Employee not listed on training matrix*

Of the 20 employees sampled, the audit team found one instance of an employee not listed on the Employee-to-Job-Function Matrix.

Requirement

AP-2.1Q, Revision 3, Section 5.4, Implement Training, states: “[9] Create a matrix or database that lists individuals who have completed job training or qualification requirements.”

Condition

Employee number 17404 was not listed on the current LLNL Employee-to-Job-Function Matrix. The condition was isolated in nature and corrected during the audit. The audit team verified the correction review of an updated Employee-to-Job-Function Matrix on April 22, 2004.

3.2 PROGRAM ADEQUACY, IMPLEMENTATION, AND EFFECTIVENESS

The audit team concluded that the quality-affecting APs, LPs, QPs, and TIPs adequately implement the QARD requirements. In addition, the team determined that LLNL has been effectively implementing the quality-affecting procedures.

4.0 ATTACHMENTS

Attachment A - Personnel Contacted

Attachment B - Summary of Audit Results

Attachment A - Personnel Contacted

Name	Organization	Pre-Audit Meeting	Contacted During Audit	Post-Audit Meeting
Bob Hartstern	BSC/QA			X
Charlie Warren	BSC/QA	X	X	X
Vic Barrish	LLNL	X	X	X
Don Bucci	LLNL		X	X
John Estill	LLNL		X	
Robert Etien	LLNL		X	
Ken Evans	LLNL		X	
Pat Fontes	LLNL	X	X	X
Gregory Gdowski	LLNL	X		X
Curtis Glover	LLNL		X	X
Leigh Gouveia	LLNL		X	
Marilyn Governor	LLNL		X	X
Axel Harris	LLNL	X	X	
Patricia Hurst	LLNL	X	X	
Ken Lee	LLNL	X	X	
Steve Mahler	LLNL	X	X	X
M. Ed Melczer	LLNL	X	X	X
Tonya Reshel	LLNL	X	X	X
Kirk Staggs	LLNL		X	
Pamela Stanworth	LLNL		X	X
Tammy Summers	LLNL	X	X	X
Frank Wong	LLNL	X	X	

Attachment B - Summary of Audit Results

QARD Section	Implementing Documents	Condition Reports	Document Adequacy	Implementation	Overall Effectiveness
1.0	033-YMP-QP 1.0, <i>Organization</i>		Adequate	Satisfactory	Effective
2.0	AP-2.1Q, <i>Personnel Training and Qualification</i>	2521	Adequate	Satisfactory	Effective
	AP-2.27Q, <i>Planning for Science Activities</i>				
	LP-2.9Q-BSC, <i>Establishment and Verification of Required Education and Experience of Personnel</i>	2519			
5.0	033-YMP-QP 2.1, <i>Preparation, Approval and Revisions of Procedures</i>	2517	Adequate	Satisfactory	Effective
	033-YMP-QP 5.0, <i>Technical Implementing Procedures</i>	2517			
6.0	AP-2.14Q, <i>Document Review</i>		Adequate	Satisfactory	Effective
	AP-6.1Q, <i>Document Control</i>	2519			
7.0 App C	AP-7.7Q, <i>Acceptance of Items and Services</i>	2519	Adequate	Satisfactory	Effective
	TIC-AC-10, <i>Q-Procurement of Analytical Services from a Non-QSL Laboratory</i>				
12.0	AP-12.1Q, <i>Control of Measuring and Test Equipment and Calibration Standards</i>		Adequate	Satisfactory	Effective
	TIP-CM-42, <i>User Verification of Gamry Potentiostats</i>				
16.0	AP-16.1Q, <i>Condition Reporting and Resolution</i>		Adequate	Satisfactory	Effective
	AP-16.4Q, <i>Causal Analysis and Corrective Action Plan Development</i>				
17.0	AP-17.1Q, <i>Records Management</i>	2517	Adequate	Satisfactory	Effective
Supp I	AP-SI.1Q, <i>Software Management</i>		Adequate	Satisfactory	Effective

Attachment B - Summary of Audit Results (continued)

QARD Section	Implementing Documents	Condition Reports	Document Adequacy	Implementation	Overall Effectiveness
Supp II	033-YMP-QP 8.0, <i>Identification and Control of Samples</i>		Adequate	Satisfactory	Effective
	033-YMP-QP 13.0, <i>Handling, Storage, and Shipping</i>				
	TIP-CM-01, <i>Accounting of Test Specimens for the Long-Term Corrosion Testing</i>				
	TIP-CM-02, <i>Receiving, Handling, and Storage of Specimens for Long-Term Corrosion Testing</i>				
	TIP-YM-03, <i>Labeling, Tracking, and Shipping of Samples</i>		Adequate	Satisfactory	Effective
Supp III	AP-SIII.1Q, <i>Scientific Notebooks</i>	2518			
	AP-SIII.3Q, <i>Submittal and Incorporation of Data to the Technical Data Management System</i>				
	AP-SIII.9Q, <i>Scientific Analyses</i>				
	AP-SIII-10Q, <i>Models</i>				
Supp V	AP-SV-1Q, <i>Control of Electronic Management of Information</i>		Adequate	Satisfactory	Effective
	033-YMP-QP 3.8, <i>Control of Electronic Management of Data</i>	2520			